PREGNANCY NOTIFICATION FORM

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| **GUIDANCE FOR THE PERSON COMPLETING THIS FORM** |
| 1. Forms must be submitted to ACCORD **within 14 days** of the site research team becoming aware of the pregnancy.
2. **If the mother experiences an SAE during the pregnancy a SAE form must be submitted to ACCORD within 24 hours of the site research team becoming aware of the SAE.**
3. **Do not include** personal identifiers (patient names, initials, dates of birth, CHI numbers, etc) on this form.
4. Do not include any supplementary information or documents unless requested by ACCORD.
5. Complete the form as far as possible. The form can be updated/signed and re-submitted as new information becomes available.
6. Any updates should be added to the original form – **DO NOT**create a new form for each update to this pregnancy notification form.
7. Forms must be submitted via email in a PDF format to **safety@accord.scot**
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| **1. REPORT DETAILS** |
|  |  |  |  |  |  |
| **Trial Name:** |  |  | **Date of Report:** |  |  |
|  |  |  |  |  |  |
| **Sponsor Number:** |  |  | **Centre ID:** |  |  |
|  |  |  |  |  |  |
| **EudraCT or ISRCTN Number:** |  |  | **Centre Name:** |  |  |
|  |  |  |  |  |  |
| **Participant ID:** |  |  | **Centre Country:** |  |  |
|  |  |  |  |  |  |
| **Date PI informed of Pregnancy:** |  |  |  |  |  |
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| **Notification of pregnancy in a female participant** | [ ]  |
| **Notification of pregnancy in a partner of a male participant** | [ ]  |

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| **2. MATERNAL INFORMATION** |
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| **Date of last menstrual period:** |  | **Expected date of delivery:** |  |  |
|  |
| **Method of contraception:** |  |  |
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| **Was contraception used as instructed?** | [ ]  Yes [ ]  No [ ]  Uncertain |
| **MEDICAL HISTORY (include information on familial disorders, known risk factors or conditions that may affect the outcome of pregnancy. If none, mark NA)** |
|  |
| **PREVIOUS OBSTETRIC HISTORY (provide details on all previous pregnancies, including termination or stillbirth)** |
|  | **Gestation Week** | **Outcome including any abnormalities** |
| **1.** |  |  |
| **2.** |  |  |
| **3.** |  |  |
| **DRUG INFORMATION (All therapies taken prior to and during pregnancy to be included. IMP/NIMP information to be captured in Section 7)** |
| **Drug Name** | **Dose and frequency** | **Route** | **Start date** | **Stop date** | **Indication** | **Treatment start (week of pregnancy)** | **Treatment stop (week of pregnancy)** |
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| **3. PRENATAL INFORMATION** |
| **Have any specific tests e.g. amniocentesis, ultrasound, maternal serum AFP been performed during the pregnancy so far?** | [ ]  Yes [ ]  No  |
| **Test/lab finding** | **Unit** | **Date** | **Value/finding** |
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| **Comment on any findings (or mark as NA)** |  |

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| **4. PREGNANCY OUTCOME** |
| **Abortion** [ ] [ ]  Therapeutic[ ]  Planned [ ]  Spontaneous | **Delivery** [ ] [ ]  Normal [ ]  Forceps/Ventouse[ ]  Caesarean  |
| **Please specify the reason for abortion and any abnormalities if known:** | **Maternal complications or problems related to the birth:** |
|  |  |
| **Date of Abortion:** |  | **Date of Delivery:** |  |
| **MATERNAL PREGNANCY ASSOCIATED EVENTS:****If the mother experiences an SAE during the pregnancy, please indicate above and complete an SAE form. This should be submitted to ACCORD within 24 hours. Email to:** **safety@accord.scot** |
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| **5. CHILD OUTCOME** |
| **Child outcome** | [ ]  Normal [ ]  Abnormal [ ]  Stillbirth  |
| **If any abnormalities please specify and provide dates** |   |
| **Sex** | [ ]  Male [ ]  Female  |
| **Length (cm)** |  |
| **Weight (kg)** |  |
| **Head circumference (cm)** |  |
| **Apgar scores** | 1min |  |
| 5mins |  |
| 10mins |  |

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| **6. ASSESSMENT OF SERIOUSNESS OF PREGNANCY OUTCOME**  |
| **Seriousness Criteria:** | [ ]  **Non serious**[ ]  **Serious** *(please tick at least one seriousness criteria below)*:[ ]  Inpatient hospitalisation or prolongation of existing inpatient hospitalisation[ ]  Involved persistent or significant disability or incapacity[ ]  Life-threatening [ ]  Stillbirth/neonate died[ ]  Mother died[ ]  Congenital anomaly/birth defect[ ]  Other significant medical event |
| **What is your assessment of the implications, if any, for the safety of study participants and how will these be addressed?** |  |

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| **7. TRIAL TREATMENT AND ASSESSMENT OF CAUSALITY OF PREGNANCY OUTCOME** |
| **Did participant receive IMP/NIMP prior/during the pregnancy?** | [ ]  Yes  | [ ]  No *if no, please proceed to section 8* |
| **Name of trial IMP/NIMP** | **Dose/****Schedule** | **Route of Administration** | **Start Date (week of pregnancy if applicable)** | **End Date****(week of pregnancy if applicable)***Tick box if ongoing* | **Is the pregnancy outcome causally related to IMP/NIMP?** |
| **1** |  |  |  |  |  | [ ]  | [ ]  Unrelated | [ ]  | Possibly Related |
| **2** |  |  |  |  |  | [ ]  | [ ]  Unrelated | [ ]  | Possibly Related |
| **3** |  |  |  |  |  | [ ]  | [ ]  Unrelated | [ ]  | Possibly Related |
| **Rationale for causality assessment:** |  |

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| **8. ADDITIONAL INFORMATION** |
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| **9. INFORMATION SOURCE FOR INITIAL REPORT** |
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| **Name / job title of person completing report:** | / |  |
|  |
| **Email:** |  | **Telephone:** |  |  |
|  |
| **PI Name** |  | **PI Signature:** | *Date:* |  |
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| **ALL Reports must be signed and dated by the Principal Investigator** *(or suitably qualified clinician listed on the delegation log)*If signatory is unavailable, the unsigned form must still be sent within 14 days of being informed |
| **10. INFORMATION SOURCE FOR FOLLOW-UP no. 1** |
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| **Name / job title of person completing report:** | / |  |
|  |
| **Email:** |  | **Telephone:** |  |  |
|  |
| **PI Name** |  | **PI Signature:** |  *Date:* |  |
|  |
| **ALL Reports must be signed and dated by the Principal Investigator** *(or suitably qualified clinician listed on the delegation log)*If signatory is unavailable, the unsigned form must still be sent within 14 days of being informed |
| **11. INFORMATION SOURCE FOR FOLLOW-UP no. 2 (for any additional follow-ups please use form CR005-T06)** |
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| **Name / job title of person completing report:** | / |  |
|  |
| **Email:** |  | **Telephone:** |  |  |
|  |
| **PI Name** |  | **PI Signature:** |  *Date:* |  |
|  |
| **ALL Reports must be signed and dated by the Principal Investigator** *(or suitably qualified clinician listed on the delegation log)*If signatory is unavailable, the unsigned form must still be sent within 14 days of being informed |
| **Original wet signature forms must be filed in the Investigator Site File (ISF).****ACCORD will retain a copy on file.** |